

EXHIBIT 11

Office Action Summary	Application No. 11/400,497	Applicant(s) ALLAWAY ET AL.	
	Examiner BAO LI	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49, 53 and 55-58 is/are pending in the application.
- 4a) Of the above claim(s) 56-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49 and 55 is/are rejected.
- 7) ☒ Claim(s) 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/18/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The response filed on August 18, 2008 has been acknowledged. In summery, claims 1-48, 50-52, 54 were canceled. Clams 49, 53, 55-58 are pending. Claims 56-58 are withdrawn from consideration. Claims 49, 53 and 55 are considered before the examiner.

Claim Rejections - 35 USC § 102

1. The rejection of claims 49 and 53 under 35 U.S.C. 102(b) as being anticipated by Samson et al. (Biochemistry, March 1996, Vol. 35, pp. 3362-3367) has been withdrawn in view of Applicants' persuasive argument that Samson et al. only teach a full length of CCR5. No fragment or CCR5 comprising the portion set forth with amino acid sequence of SEQ ID NO: 7 is taught or suggested.
2. The rejection of claims 49, 53 and 55 under 35 U.S.C. 102(e) as being anticipated by US Patent Nos. 6,025,154 A, 6.511, 826B2 and 6,800,729 to Li et al. and Patent No 6,265,184B1 to Gray et al. has been moot in view of new grounds of rejections upon further considering the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. Claims 49 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Nos. 6,025,154 A to Li et al., or US Patent No. 6.511, 826B2 to Li et al. or US Patent No. 6, 800,729 to Li et al. and Patent No 6,265,184 B1 to Gray et al.
5. In the response, Applicants argue the claimed polypeptide being a portion of a sequence of CCR5 rather than the full length CCR5 that includes the particular sequence set forth in SEQ ID NO: 7. Therefore, the cited references are not 102 references that anticipate the claims.

6. Applicants' argument have been respectfully considered; however, Applicants are reminded that a reasonable interpretation of the broad scope of claims 49 and 55 is not limited to the particular amino acid sequence of SEQ ID NO: 7, it is directed to any size of CCR5 fragment that is less than the full length in size. As long as it comprising the SEQ ID NO: 7, it could be any fragment of CCR5 even if with one or more than one amino acid less than the full length CCR5.
7. All cited references teach not only the full length of the polypeptide of CCR5, but also variable fragments derived from the CCR5 obviously comprising the claimed polypeptide set forth with SEQ ID NO: 7. For example, US Patent Nos. 6,025,154 A, 6,511, 826B2 and 6,800,729 all to Li et al teach to make a polypeptide with deduced amino acid sequence comprising any portion of such polypeptide with at least 20 or 50 amino acids of SEQ ID NO: 2, wherein the SEQ ID NO: 2 is the same identical CCR5 to the claimed polypeptide that is used to derive the SEQ ID NO: 7. Patent "184A" teaches that a fragment of CCR5 identical to the claimed CCR5 polypeptide can be made with the 2nd extracellular domains of CCR5, wherein the claimed SEQ ID NO: 7 is in the 2nd extracellular domain. Therefore, the cited references teach each of the limitations required by the claimed polypeptide. Therefore, although the cited references do not explicitly teach the fragments of CCR5 comprising SEQ ID NO: 7, it is still obvious that one of the disclosed CCR5 fragments would be inherently comprise the SEQ ID NO: 7 or it would have been obvious for a person ordinarily skilled in the art to make a polypeptide comprising the SEQ ID NO: 7 with a reasonable expectation of success. Moreover, the fact of a characteristics as a necessarily feature inherently presented in the structurally same polypeptide is enough for inherently anticipation, even if that fact may be unknown at the time prior to the invention. Consideration of inherent properties is also a part of proper consideration of the invention as a whole for the obvious type of rejection.
8. Therefore, it would have been obvious for any person ordinarily skilled in the art to make a fragment of CCR5 necessarily comprising the portion of the 2nd extracellular domain set forth with SEQ ID NO: 7 with a reasonable expectation of a success.
9. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

Claim 53 is allowable. However, it is not in condition for allowance, because it depends on the rejected claim 49. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/

Examiner, Art Unit 1648



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/400,497	04/07/2006	Graham P. Allaway	51320-AAA/JPW/AG	3119
23432 7590 11/10/2008 COOPER & DUNHAM, LLP 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036				
			EXAMINER LI, BAO Q	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 11/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.